



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

DEC 30 1997

Raphael Henkin, Ph.D.  
Del Mar Avionics  
1621 Alton Parkway  
Irvine, CA 92606-4878

Re: K971696  
Models 471/472 Sentinel Solid-State Event/Loop Recorders  
Regulatory Class: II (two)  
Product Code: 74 DXH  
Dated: September 30, 1997  
Received: October 1, 1997

Dear Dr. Henkin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

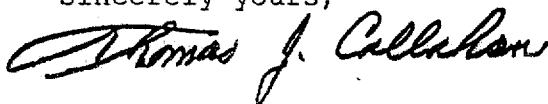
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Raphael Henkin, Ph.D.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, reading "Thomas J. Callahan". The signature is fluid and cursive, with the first name "Thomas" being the most prominent part.

Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



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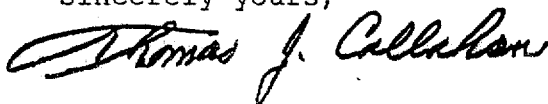
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Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

TO: C. Ho, PH.D.  
FDA  
FROM: E. Crespin  
Del Mar Avionics  
714/250-3200

Del Mar Avionics  
Re: K971696  
Sentinel™ Solid-State Event/Loop Recorders  
Models 471/472

## APPENDIX B

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510(k) Number (if known): K971696

Device Name: Models 471/472 Sentinel™ Recorders

Indications For Use:

The Del Mar Avionics Models 471/472 Sentinel Recorders are ambulatory Electrocardiographic (ECG) recorders intended to acquire multiple brief episodes of ECG information. Acquisition of ECG information is initiated by the patient, normally in response to encountered symptoms.

The Model 471 Sentinel Recorder acquires a single channel of ECG.

The Model 472 Sentinel Recorder acquires one or two channels of ECG.

The Models 471 and 472 Sentinel Recorders are intended to be used as an ECG Cardiac Monitoring Instrument.

The Models 471 and 472 Sentinel Recorders are not suitable for monitoring infants weighing less than 22 (10 kg) pounds.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDHR, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Cardiovascular, Respiratory,  
and Neurological Devices

Prescript on Use  
(Per 21 C.F.R 801.109)

510(k) Number K971696

OR

Over-The-Counter Use

(Optional Format 1-2-96)